

**HL7 SPL Working Group Process Communication Forum Telecon  
Wednesday, June 2, 2010**

Check out the SPL Working Group WIKI @:

<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

**Meeting Minutes:**

**SPL documents with missing medication guides or incorrectly coded medication guides**

Start using Medguide LOINC code if you aren't already.

FDA will be contacting each company that has incorrectly coded SPL or aren't including MedGuides. Contact will be made first via e-mail. If there's no response, the Review Division will be asked to get involved.

**ER/DL Subteam**

**Assignment of FEI numbers**

- District Monitors assign FEI numbers. Once DRLS had all its questions answered, they should send on the request to the DM.
- The DRLS group may ask you to submit a Labeler Code Request. This is not required for the assignment of an FEI number.

This text may be useful in an e-mail response to DRLS:

<Company X. is an international site that will not distribute finished product in the USA Market. We believe that we are following proper procedures according to FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing and advice previously provided by DRLS. Therefore, a Labeler Code is not required and a request will not be submitted for the facility.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072339.pdf>

- Request an email notification of the FEI. However, you may need to keep asking if the number has been assigned, in case DRLS doesn't remember to e-mail.
- Once a sponsor receives an FEI number, he/she should update the Establishment Registration SPL and resubmit. This will then update the eList system and the Drug Firm

Annual Registration Status website. The Drug Firm Annual Registration Status website is only updated once the sponsor resubmits the Establishment Registration electronically.

### API Materials being held at the borders

Inspectors do not currently have access to the eList data. This is causing huge problems with materials being held at the borders.

### **Device subteam**

Devices page on RCRIM WIKI:

[http://wiki.hl7.org/index.php?title=Medical\\_Product\\_Information\\_\(SPLr5\)](http://wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5))

SPL Device Subteam leader: [myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com)

Meetings to be held alternate Thursdays

Next meeting scheduled for June 3, 2010; meetings occur every other Thursday, 10:30 ET

Telecom: 770-657-9270 . Passcode: 745896

### **FYI**

Minutes of previous Process Team meetings are here:

<http://spl-work-group.wikispaces.com/Process+Communications+Forum>

FDA is planning for product/type specific training sessions

First sessions are likely to be:

- Cosmetics that are also drugs
- Homeopathic substances